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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,709	06/20/2002	Nicklas Stromberg	P/2432-44	4724
32172	7590	04/19/2004	EXAMINER	
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP 1177 AVENUE OF THE AMERICAS (6TH AVENUE) 41 ST FL. NEW YORK, NY 10036-2714			GRASER, JENNIFER E	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,709

Applicant(s)

STROMBERG ET AL.

Examiner

Jennifer E. Graser

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/19/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

The instant specification also contains several amino acid sequences throughout the specification which are encompassed by the definitions for nucleotide/amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) and which must conform with the sequence rules for all applications that include nucleotide/amino acid sequences. The sequence identifiers obtained through conformance (paper submission and CRF/electronic) must be inserted into the body of the specification directly following each sequence.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the claim fails to adequately describe the structure of the composition which is claimed. The claim should provide any structural properties, such as the amino acid sequence of the peptide, by Sequence Identification number, which would allow for one to identify the protein without ambiguity. The mere recitation of the length of the peptide, i.e, decapeptide, which

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comprises two arginine residues in any location, does not adequately define the claimed peptides. Claim 1 is also vague and indefinite due to the phrase "An oligopeptide protecting against". The phrase should recite "An oligopeptide for protecting against".

Claim 2 is vague and indefinite due to the language "comprised by the sequence". The claim should be changed to "comprising the sequence of" if open language is intended, or, more preferably, "consisting of the sequence of" if the claim is limited to the peptide set forth in the claim. Claim 2 must also include the sequence identification number of the sequence recited, i.e, SEQ ID NO:13. Any amino acid sequence over 4 amino acids should be referred to by a sequence identification number.

Claim 3 is vague and indefinite because it recites "[t]he oligopeptide of claim 2 ArgGlyArgProGln" yet claim two comprises a much larger sequence. The claim as written does not appear to be properly dependent. Additionally, the sequence identification number of the sequence, i.e, SEQ ID NO:1" must be recited in the claim.

Claim 4 is vague and indefinite because it is unclear whether the peptides are limited to the sequences set forth in the claims, or if larger polypeptides which comprise these peptides are encompassed. Claim 2 uses the open language 'comprised by' which allows for much larger sequences than are claimed. It appears from the instant specification that Applicants intend to claim the specific sequences. If such is the case, then claim 2 should be amended from "comprised by the sequence to "consisting of the sequence" in order to avoid reading on much larger peptides, i.e., full-length PRP-1 which includes these oligopeptides.

Claim 4 must be amended so as to recite the proper sequence identification number after each sequence, i.e., SEQ ID NO:1, SEQ ID NO:2....SEQ ID NO:12", etc..

Claims 5-17 are vague and indefinite because it is unclear what amount is encompassed by the phrase "prevention-effective amount". The specification fails to define this amount. Clarification is requested.

Claim 7 recites the limitation "wherein the carrier is". There is insufficient antecedent basis for this limitation in the claim. The preceding claim does not recite "a carrier". Correction is required.

Claims 8 and 15-17 are vague and indefinite because it is unclear what is being claimed. The claims recite "The manufacture of a medicament". Is this a method step? If so, the claims are incomplete because they do not comprise any steps. See MPEP § 2172.01. Additionally, it is unclear what is meant by the term "medicament".

Claim Rejections - 35 USC § 112-Scope of Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific oligopeptides recited in dependent claims 2-4 and which are recited in SEQ ID Nos: 1-13, does not reasonably provide enablement for any pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide or decapeptide which comprises two arginine residues in any location. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches specific peptides which are acidic peptides derived from PRP-1. The specification teaches that these specific peptides possess qualities which would be effective in treating dental caries. The instant claims allows for the inclusion of any amino acids as long as there are two arginine residues present, i.e. 8 of the decapeptide residues could be tryptophan or any of the other known amino acids. The specification is not enabled for the scope of this invention. It is also unpredictable if any of these other oligopeptides would possess properties effective in preventing or treating dental caries. The claims should be limited to the specific peptides generated by Applicants. *Genentech Inc. v. Novo Nordisk A/S* (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."

Claim Rejections - 35 USC § 112

6. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-17 are drawn to methods for *preventing* dental caries comprising the oral administration of a preventive-effective amount of oligopeptides. The recited compositions comprising said oligopeptides, manufacture of medicaments, and oligopeptides also recite "protecting or preventing dental caries". The instant specification does not provide any data that the oligopeptides recited in the instant claims can *prevent* dental caries. The specification teaches that the prior art teaches that commensal *Actinomyces* and *Streptococcus* species transform acidic PRPs to small-size peptides which are transformed into ammonia by oral bacteria. The ammonia thus formed raises the pH at the dental surface and thereby protects the surface against caries. The inventors have generated acidic arginine containing peptides derived from PRP. The specification provides data on the biochemical nature of the oligopeptides which were generated. However, the specification fails to provide evidence that any of these peptides can protect or prevent dental caries. However, the peptides most likely could "treat" dental caries. The claims should be limited to treatment methods.

Claim Rejections - 35 USC § 112-Written Description

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth an oligopeptide consisting of an amino acid sequence selected from the group consisting of: SEQ ID NOs: 1-13 and therefore the written description is not commensurate in scope with a claim drawn to any pentapeptide, hexapeptide, heptapeptide, octapeptide, nonapeptide or decapeptide which comprises two arginine residues in any location.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of the encompassed oligopeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The oligopeptide itself is required.

Therefore only an oligopeptide consisting of an amino acid sequence selected from the group consisting of: SEQ ID NOs: 1-13, but not the full breadth of the claims meets the written description provisions of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Shafer (WO 94/0753).

Shafer teaches antimicrobial peptides which contain two arginine residues and are used in the treatment and prevention of gingivitis and periodontitis. It is disclosed that the oligopeptides may be from five (pentapeptide) to about twenty-six amino acids in length. See page 9, lines 25-28.

Status of Claims:

10. No claims are allowed. 'An oligopeptide for treating dental caries **consisting of** an amino acid sequence selected from SEQ ID Nos: 1-13' is free of the prior art.

Methods of treating dental caries using said oligopeptides would also be allowed.

Applicants should limit the scope of their claims to the specific oligopeptides, i.e., used the closed language 'consisting of' and recite 'treating' instead of 'protecting/preventing'.

11. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the

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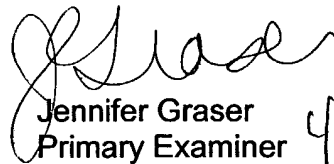
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Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.


Jennifer Graser
Primary Examiner
Art Unit 1645
4/15/04